510(k) SUMMARY

The 510(k) Summary is submitted as required by Section 807.92(a)

AUG 10 2006

Submitter Name:	Volcano Corp.
Contact Person:	Michelle J. Badal, RAC Manager, Regulatory Affairs
Address:	2870 Kilgore Road Rancho Cordova, CA 95670
Phone Number:	916-231-4497
Fax Number:	916-638-2647
Date Prepared:	May 1, 2006
Device Trade Name:	**Volcano s5i Family of Imaging Systems**
Device Common Name:	Ultrasonic imaging system
Classification Name, Number, Product Code:	Ultrasonic pulsed echo imaging system 21 CFR 892.1560, Product Code: IYO

Predicate Device:

Cathscanner III Imaging System cleared under K944004; ColorFlo Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K963290; Resolve Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K965223; InVision Imaging System cleared under K031148, and Volcano s5 Imaging System cleared under K051920.

Device Description:

The Volcano s5i Family of Imaging Systems consists of the imaging catheter, the patient interface module, and the system console. The system console gathers and displays high-resolution intraluminal images that can be analyzed both qualitatively and quantitatively. In addition to supplying diagnostic information, the Volcano s5i Imaging Systems can be an adjunct to interventional therapies, such as balloon angioplasty. With ChromoFlo® a two-dimensional color map of relative blood flow is overlaid on the grayscale image, providing additional information for vessel analysis. The In-Line Digital option displays a two-dimensional, 360° rotations and longitudinal view of the vessel. The Volcano s5i Imaging System software provides an option for connectivity with third party fluoroscopic imaging systems. The software option simplifies the Cardiac Catherization Lab workflow with the

fluoroscopic imaging systems by, 1) automatically synchronizing the patient demographic information (patient name, date of birth, DICOM attributes, etc.) from the fluoroscopic imaging system with the Volcano s5i Imaging System, 2) providing a remote access to commonly used IVUS functions from the fluoroscopic imaging system user interface.

The imaging catheters are all marketed under separate premarket notifications; Visions catheter K982329, Avanar catheter K000820 and Eagle Eye Gold K031346.

Intended Use:

Volcano s5i Family of Imaging Systems is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

Performance Data:

Applicable testing was performed to evaluate the modifications to the Volcano s5i Family of Imaging Systems. The test results were found to be acceptable as required by the respective test plans and protocols.

Conclusion:

The testing reported in this 510(k) establishes the device is safe and effective for its intended use and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

Ms. Michelle J. Badal, RAC
Manager, Regulatory Affairs
Volcano Corp.
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K061215
Trade/Device Name: Volcano s5i Family of Imaging Systems
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO
Dated: July 7, 2006
Received: July 10, 2006

Dear Ms. Badal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061215

Device Name: Volcano s5i Family of Imaging Systems

Indications for Use:

The Volcano s5i Family of Imaging Systems is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo® is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061215

(Posted November 13, 2003)